

Amendment and Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure

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Serial No.: 09/847,670

Confirmation No.: 4815

Filed: May 2, 2001

For: HEPATITIS C VIRUS HELICASE CRYSTALS, CRYSTALLOGRAPHIC STRUCTURE AND METHODS**Remarks**

The Office Action mailed December 9, 2003, has been received and reviewed. Claims 32-34 and 36-37 having been canceled, claims 31, 35, 42-43, 47-52, and 58-59 having been amended, and claims 60-61 having been added, the pending claims are claims 31, 35, 38-43, and 47-61. Claims 31, 35, and 47-48 have been withdrawn from consideration by the Examiner.

Claims 31 and 33 have been amended to delete the recitation "molecule or molecular complex." Claims 31, 33, and 58-59 have been amended to recite that "the amino acid sequence of the Hepatitis C virus helicase is SEQ ID NO:1," which is supported, for example, by originally filed claims 39 and 41. Claims 42 and 49-52 have been amended to recite crystalline Hepatitis C virus helicase or a crystal that "effectively diffracts x-rays to a resolution of 1.5 Å to 3 Å," which is supported by the specification at, for example, page 30, line 17 ("1.5-3 Å resolution x-ray data"), page 13, line 29 ("2.0 Å resolution"), and page 14, line 1 ("1.8 Å data"). Claim 43 has been amended to depend from any of claims 38-41. Claim 47 has been amended to recite a "unit cell containing two molecules in an asymmetric unit," which is supported, for example, by originally filed claim 38. Claim 48 has been amended to recite a "unit cell containing one molecule in the asymmetric unit," which is supported, for example, by originally filed claim 40.

New claims 60-61 are supported by the specification at, for example, page 40, lines 6 and 25, respectively.

Reconsideration and withdrawal of the rejections are respectfully requested.

Interview Summary

Applicants thank Examiners Carolyn L. Smith and Ardin H. Marschel for granting a telephone interview to Applicants' Representatives, Loren D. Albin and Ann M. Mueting, on February 10, 2004.

The rejection of claims 55-57 under 35 U.S.C. §112, first paragraph, for allegedly including new matter and lacking enablement, was discussed. First, the Examiner considered the

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recitation "comprising atoms arranged in a spatial relationship represented by" to be new matter. Applicants' Representatives noted that page 7, lines 11-12, of the Amendment and Response submitted October 16, 2003 pointed to "the specification at, for example, page 9, lines 11-22" as support for claims 55-57. Applicants' Representatives also argued that one of skill in the art, in view of the specification, would be enabled to make and use the crystals recited in claims 55-57. The Examiner agreed to withdraw the rejection of claims 55-57 under 35 U.S.C. §112, first paragraph.

Further, Applicants' Representatives argued that the specification provides adequate support for claims 38-41 to satisfy the written description requirement under 35 U.S.C. §112, first paragraph, and the Examiners agreed to withdraw the written description rejection of claims 38-41.

Finally, the patentability of claims 58-59 was discussed, but no agreement was reached.

Objection to the Title

The Examiner objected to the title for reciting "methods." Applicants respectfully note that method claims are currently pending. Applicants will provide any appropriate amendments to the title upon receipt of a Notice of Allowance.

Rejections under 35 U.S.C. §112, First Paragraph

New Matter

The Examiner rejected claims 55-57 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner considered the recitation "comprising atoms arranged in a spatial relationship represented by" to be new matter. Applicants thank the Examiner for reconsidering and agreeing to withdraw the

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rejection of claims 55-57 under 35 U.S.C. §112, first paragraph, for allegedly including new matter, as discussed herein above in the Interview Summary.

Enablement

The Examiner rejected claims 42-43, 49-50, 52, and 55-59 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 43 having been amended to depend from any of claims 38-41, Applicants respectfully submit that the rejection of claim 43 has been obviated. Applicants thank the Examiner for reconsidering and agreeing to withdraw the rejection of claims 55-57 under 35 U.S.C. §112, first paragraph, for lack of enablement, as discussed herein above in the Interview Summary.

Reasons for patentability of claims 42, 49, 50, and 52 (as amended) and claims 58-59 (as amended) are discussed separately herein below.

Written Description

The Examiner rejected claims 38-43 and 49-59 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants thank the Examiner for reconsidering and agreeing to withdraw the rejection of claims 38-41 under 35 U.S.C. §112, first paragraph, as discussed herein above in the Interview Summary. Applicants respectfully submit that claims 38-41 are now in condition for allowance. Further, claim 43 having been amended to depend from any of claims 38-41, Applicants respectfully submit that claim 43 is also in condition for allowance.

Moreover, Applicants respectfully submit that claims 53-57 satisfy the written description requirement under 35 U.S.C. §112, first paragraph, for reasons similar to those for claims 38-41. Applicants respectfully request that the Examiner reconsider and withdraw the

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rejection of claims 53-57 under 35 U.S.C. §112, first paragraph, and pass claims 53-57 on to allowance.

Claim 51 recites a crystal of Hepatitis C virus helicase, wherein the Hepatitis C virus helicase comprises amino acid sequence SEQ ID NO:1, with the proviso that at least one cysteine or methionine is replaced with selenocysteine or selenomethionine, respectively.

Claims 51 has been amended to further recite that the crystal effectively diffracts x-rays to a resolution of 1.5 Å to 3 Å. Thus, Applicants respectfully submit that the recitations of claim 51 (as amended) are sufficient to convey the claimed invention to one of skill in the art, and therefore, satisfy the written description requirement. Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claim 51 under 35 U.S.C. §112, first paragraph.

Reasons for patentability of claims 42, 49, 50, and 52 (as amended) and claims 58-59 (as amended) are discussed separately herein below.

Claims 42, 49, 50, and 52

The Examiner rejected claims 42, 49, 50, and 52 under 35 U.S.C. §112, first paragraph, for lack of written description and lack of enablement. Applicants respectfully traverse the rejection.

Claim 42 recites crystalline Hepatitis C virus helicase having amino acid sequence SEQ ID NO:1. Claim 49 recites crystalline Hepatitis C virus helicase wherein the amino acid sequence of the Hepatitis C virus helicase is SEQ ID NO:1. Claim 50 recites a crystal of Hepatitis C virus helicase, wherein the Hepatitis C virus helicase comprises amino acid sequence SEQ ID NO:1. Claim 52 recites a crystal of Hepatitis C virus helicase, wherein the Hepatitis C virus helicase consists of amino acid sequence SEQ ID NO:1. Claims 42, 49 50, and 52 have each been amended to further recite that the crystalline Hepatitis C virus helicase or the crystal "effectively diffracts x-rays to a resolution of 1.5 Å to 3 Å." Thus, Applicants respectfully submit that the recitations of claims 42, 49, 50, and 52 (as amended) are sufficient to convey the claimed invention to one of skill in the art, and therefore, satisfy the written

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description requirement. Further, Applicants respectfully submit that one of skill in the art would be enabled, without undue experimentation, to make and use the crystals or crystalline Hepatitis C virus helicase recited in claims 42, 49, 50, and 52 (as amended).

Applicants respectfully request that the Examiner reconsider and withdraw the rejections of claims 42, 49, 50, and 52 under 35 U.S.C. §112, first paragraph.

Claims 58 and 59

Claims 58 and 59 each recite a crystal of Hepatitis C virus helicase prepared by the recited methods of growing a crystal (i.e., product by process claims). Claims 58 and 59 have each been amended so that the methods of growing a crystal include using "Hepatitis C virus helicase having amino acid sequence SEQ ID NO:1."

Thus, Applicants respectfully submit that the recitations of claims 58 and 59 (as amended) are sufficient to convey the claimed invention to one of skill in the art, and therefore, satisfy the written description requirement. Further, Applicants respectfully submit that one of skill in the art would be enabled, without undue experimentation, to make and use the crystals recited in claims 58 and 59 (as amended).

Moreover, Applicants note that the United States Patent and Trademark Office issues claims directed not only to methods of growing crystals of proteins, including, for example, U.S. Pat. Nos. 4,833,233, claims 5-18 (Carter, Exhibit A); 5,585,466, claims 1-13 and 15-23 (Carter, Exhibit B); 6,087,478, claim 5 (Vinkemeier et al., Exhibit C); 6,090,609, claims 5 and 7 (Luo et al., Exhibit D); 6,434,489, claims 5-15, 17-26, and 28-37 (Lesburg et al., Exhibit E); 6,524,589, claims 5-10 (Reichert et al., Exhibit F); and 6,689,595, claim 1 (Benson, Exhibit G), but also claims directed to crystals of proteins prepared by recited methods (i.e. product by process claims) including, for example, U.S. Pat. Nos. 5,585,466, claims 14 and 24 (Carter, Exhibit B); 6,434,489, claims 16, 27, and 38 (Lesburg et al., Exhibit E); and 6,689,595, claim 6 (Benson, Exhibit G).

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Based on the remarks presented herein above, Applicants respectfully request that the Examiner reconsider and withdraw the rejections of claims 58 and 59 under 35 U.S.C. §112, first paragraph.

New Claims

New claims 60 and 61 each recite a crystal of Hepatitis C virus helicase, wherein the amino acid sequence of the Hepatitis C virus helicase is SEQ ID NO:1. New claim 60 further recites that the crystal is about 0.12 x 0.12 x 0.05 mm in size. New claim 61 further recites that the crystal is about 0.4 x 0.4 x 0.2 mm in size. Applicants respectfully submit that new claims 60-61 are patentable for reasons similar to those discussed herein above for the patentability of, for example, claims 31, 33, 58, and 59.

Applicants respectfully request that the Examiner enter, consider, and pass new claims 60-61 on to allowance.

Request for Rejoinder

Pending claims 31 and 35, directed to methods for crystallizing, have been withdrawn from consideration by the Examiner. Applicants note that claims 31 and 35 (as amended) recite the language from claims 58 and 59 (as amended), respectively, which are directed to crystals *per se*. Upon an indication of claims 58 and 59 being allowable, Applicants respectfully request that claims 31 and 35 also be rejoined, examined, and passed on to allowance pursuant to M.P.E.P. §821.04. See, for example, *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fec. Cir. 1995) and *In re Brouwer*, 77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996).

Further, pending claims 47 and 48, which are directed to methods of using crystals, have been withdrawn from consideration by the Examiner. Applicants note that claims 47 and 48 (as amended) recite the language from claims 38 and 40, respectively, which are directed to crystalline Hepatitis C virus helicase. Upon an indication of claims 38 and 40 being allowable, Applicants respectfully request that claims 47 and 48 be rejoined, examined, and

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passed on to allowance pursuant to M.P.E.P. §821.04. See, for example, *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, 77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996).

Summary

It is respectfully submitted that all the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
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March 9, 2004
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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Commissioner for Patents, Mail Stop AF, P.O. Box 1450, Alexandria, VA 22313-1450, on this 9 day of MARCH, at 2:11 PM (Central Time).

By: Suzanne M. Herzer
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